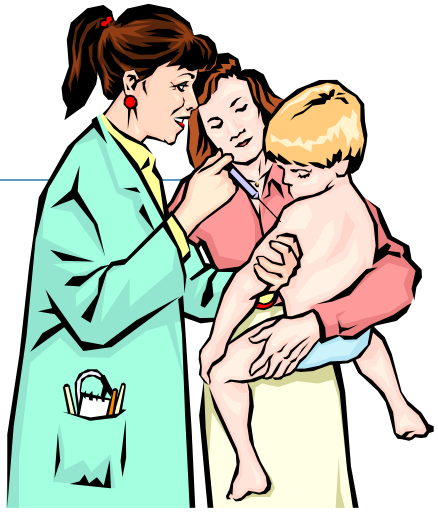
VFC UPDATE
'SPECIAL EDITION'

CDPHE



- *Hib vaccines revisited*
- *Transport of Varicella-containing vaccines*
- *A message from Joni Reynolds*

HIB VACCINES-REVISITED

The Vaccines for Children Program is finding there are some practices who still have not returned to the standard recommendations for administration of Hib vaccine. The shortage of this vaccine may have contributed to confusion regarding the schedule. This shortage was resolved in early 2010 and there is now an adequate supply of Hib vaccine. Please follow the schedules as suggested by ACIP and published by CDC.

NOTE: This is a reprint of the announcement that came from the CDC during the week of September 18, 2009.

The Immunization Program has gotten many questions regarding the use of Hiberix and other Hib vaccines over the last few weeks, and in an effort to help clarify that information:
The following information is reprinted from the MMWR weekly dated September 18, 2009 / 58 (36); 1008-1009.

Hiberix® is licensed for use as the booster (final) dose for Hib vaccination for children aged 15 months through 4 years (before the 5th birthday) who have received a primary Hib vaccination series of 2 or 3 doses (depending on the formulation of the primary series vaccines). **ACIP recommends Hib booster dosing at ages 12 through 15 months. To facilitate timely booster vaccination, Hiberix® and other Hib conjugate vaccines can be administered as early as age 12 months**, in accordance with Hib vaccination schedules for routine and catch-up immunization. Hiberix® is not licensed for the primary Hib vaccination series; however, if Hiberix® is administered inadvertently during the primary vaccination series, the dose should be counted as a valid PRP-T dose that does not need to be repeated if it was administered according to schedule. In these children, a total of 3 doses will complete the routine primary series.

Children aged 12 months through 4 years (before the fifth birthday) who did not receive a booster because of the recent shortage of Hib vaccines should receive a booster with any of the available Hib-containing vaccines at the earliest opportunity. With licensure of Hiberix® and anticipated distribution, the increased supply of Hib-containing vaccines will be sufficient to support a provider-initiated notification process to contact all children whose Hib booster dose had been deferred. When feasible and when vaccine supply in the office is sufficient, vaccination providers should review electronic or paper medical records or immunization information system (e.g., registry) records to identify and recall children in need of a booster dose. If supplies are not adequate, providers should continue to follow previous recommendations to provide the booster dose at the child's next regularly scheduled visit.

To read the entire article in the MMWR, go to:
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm

There are handy Hib Vaccine Dosage Schedules inside>>>>>>>>>

Colorado Dept. of Public Health and Environment, Immunization Program

HIB VACCINE DOSE SCHEDULE

Schedule Based on Age at Time of First Dose

Vaccine	Age at 1st Dose (months)	Primary Series	Booster Dose
ActHib®			
3-dose primary	2-6	3 doses, 2 months apart	at 12-15 months* ¶
series + booster	7-11	2 doses, 2 months apart	at 12-15 months* ¶
Note: Hib component	12-14	1 dose	2 months later
of Pentacel® (DTaP-IPV-Hib)	15-59	1 dose	-----
PedvaxHib®			
2-dose primary	2-6	2 doses, 2 months apart	at 12-15 months* ¶
series + booster	7-11	2 doses, 2 months apart	at 12-15 months* ¶
	12-14	1 dose	2 months later ¶

* 2 months from previous dose

NOTE: The booster (final) dose can be given using any brand of Hib or Hib-containing combination vaccine (ActHib®, Pentacel®, PedvaxHib®, Comvax®, Hiberix®).

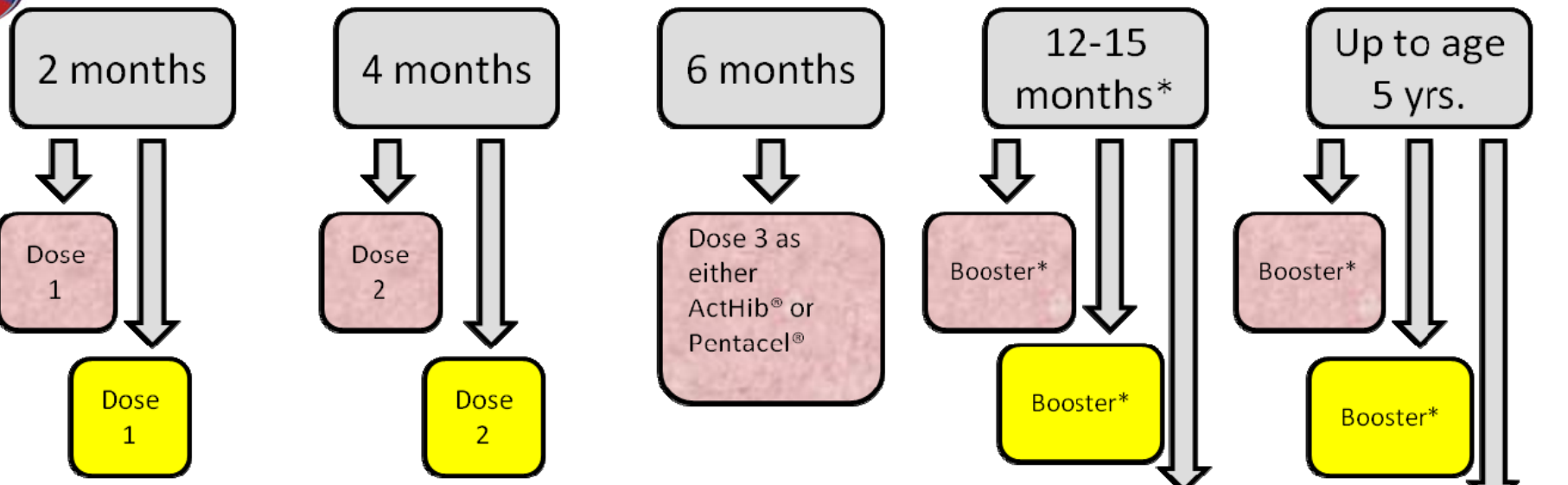
¶Hiberix® (single-antigen Hib):

- Recommended for children 12 months through 59 months of age
- Use only for the booster (final) dose of Hib. **Do not use for primary series doses**
- Use only in children who previously received at least one dose of a Hib product approved for the primary series doses, either ActHib®/Pentacel® or PedvaxHib®/Comvax®.

Colorado Dept. of Public Health and Environment

HIB VACCINE DOSE SCHEDULE

Immunization Program



ActHib®/ Pentacel®

ActHib'/Pentace 'is a 4 dose series given routinely at 2,4, and 6 months, with a booster at 12 months.

PedvaxHib® Or Comvax®

PedvaxHib'/Comvax' is a 3 dose series, usually given with primary doses at 2, and 4 months, with the booster given at 12 months.

NOTE: ***If an infant/child does not start the series on schedule, fewer doses may be needed.*** *Check the ACIP "Catch-up Schedule for Persons Aged 4 Months through 18 Years Who Start Late ..." for information on the total number of Hib doses needed.*

ActHib®/ Pentacel®

PedvaxHib®

Hiberix®

* The booster (final) dose can be given using any brand of Hib or Hib-containing combination vaccine (ActHib*, Pentacel*, PedvaxHib*, Comvax*, Hiberix*).

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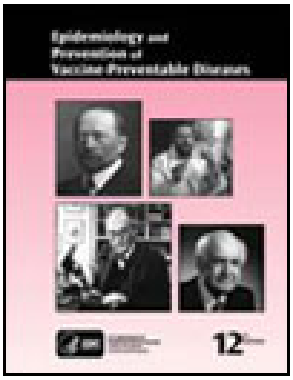
CHANGES TO INSTRUCTIONS ON TRANSPORT/SHORT-TERM STORAGE OF VARICELLA-CONTAINING VACCINES



"Transporting Varicella-Containing Vaccines to Off-Site Clinics"

Since April there has been a buzz going around the vaccine community about changes to how varicella-containing vaccines should be transported for use in off-site clinics, or packaged for short term storage in the event of a power failure, or mechanical breakdown. The Colorado Immunization Program has been waiting for final guidance from the Centers for Disease Control and Prevention (CDC) before publishing this information. Guidance was received when the 12th Edition of the Epidemiology and Prevention of Vaccine Preventable Diseases the "Pink Book" was released.

The newest edition of the "Pink Book" has a new chapter (Chapter 5) on Storage and Handling of Vaccines, and the following guidance is found on pages 72 and 73.

Transporting Varicella-Containing Vaccines to Off-Site Clinics

- CDC strongly discourages transport of varicella-containing vaccines to off-site clinics.
- Varicella-containing vaccines (VAR, Varivax; MMRV, ProQuad; ZOS, Zostavax) are fragile.
- If these vaccines must be transported to an off-site clinic, the vaccine manufacturer recommends they be transported and stored at refrigerator temperatures, between 35°F and 46°F (2°C to 8°C), for no more than 72 continuous hours prior to reconstitution.
- Packing and temperature monitoring as outlined in Appendix C {*page C-5*} also applies.
- Vaccine stored between 35°F and 46°F (2°C to 8°C) that is not used within 72 hours of removal from the freezer should be discarded.
- Discard reconstituted vaccine if it is not used within 30 minutes.
- Varicella-containing vaccines cannot be refrozen.
- Providers should contact their immunization program for advice and details.

Having a patient pick up a dose of vaccine (e.g., zoster vaccine) at a pharmacy and transporting it in a bag to a clinic for administration is not an acceptable transport method for zoster vaccine or **any other vaccine**.

Further documentation can be found in the package inserts for the following vaccines, all manufactured by Merck: MMRII, Varivax®, MMRV (ProQuad®), and Zostavax®.

http://www.vaccinesafety.edu/package_inserts.htm

The attached Frequently Asked Questions (FAQ's) have been developed to assist providers in understanding why the change, and hopefully assist in making adjustments to their Vaccine Management plans.

FAQ'S FOR TRANSPORTING FROZEN VACCINES

Q. Why is this change in guidance happening now?

A. It has come to the attention of the Vaccine Supply and Assurance Branch (VSAB) at the CDC, through vaccine effectiveness studies that excessively cold temperatures (in excess of –58°F (-50°C)) may actually be harmful to varicella-containing vaccines, or vaccines that can be stored in the freezer (such as MMRII). Such temperatures can be generated by transporting or storing frozen vaccines on dry ice. Therefore, the VSAB does not recommend the use of dry ice in the transport of varicella-containing vaccines, or frozen MMRII.

Q. But the vaccine we receive from the manufacturer arrives on dry ice?

A. Merck is changing the way they are going to ship their Varicella-containing vaccines They are replacing the dry ice with 6 refrigerant packs. As with all vaccines, the temperature monitoring device(s) in the shipments from Merck must be evaluated to determine if the vaccine has been exposed to temperatures out of the normal storage temperatures for the vaccine(s). The "freeze" monitor must be activated, to check for temperature stability once the vaccine has arrived in your office. For more information from Merck, see the information found on the next two pages.

Q. What guidelines have the CDC and Merck written for the transport of frozen vaccines (MMRII, Varivax®, MMRV-ProQuad®, and Zostavax®) to off-site clinics?

A. The CDC and the manufacturer (Merck) recommends these vaccines be transported and stored at refrigerator temperatures, between 35°F and 46°F (2°C to 8°C), for no more than 72 hours. The package inserts (updated in December 2010 for Zostavax® and April 2011 for all other Merck vaccines), clearly state to not use dry ice as it could subject the vaccines to temperatures lower than –58°F.

Q. So…, what is the proper way to pack vaccines for transport to another location?

A. See the attached document demonstrating how to appropriately pack vaccines for transport.

Q. So…. if we follow the guidelines from the CDC, the frozen vaccine(s) might be transported to an off-site clinic?

A. Yes, this is the proper way to transport ALL vaccines. You need to be very careful to transport ***only*** the amount of varicella-containing vaccine that you expect to use, to minimize wastage.

Q. What is the amount of time that frozen vaccines can stay at refrigerated temperatures, before they must be "wasted"?

A. Frozen vaccines that have been placed in a refrigerator, must be marked "Use within 72 hours of removal from the freezer". After that time, the vaccines must be labeled "DO NOT USE", removed from the refrigerator, and reported as wasted vaccines. This is why it is so important to only transport the minimum amount of frozen vaccine off-site.

Q. Could our satellite clinic receive varicella-containing vaccines directly from the manufacturer?

A. That might be an option. Please contact the Colorado VFC program to discuss this.

Q. What about our vaccine management plan? Do we need to change that?

A. Yes, please be certain to update your vaccine management plan to reflect this new guidance.

VARIVAX®
(VARICELLA VIRUS VACCINE LIVE)

A new shipping package for VARIVAX

Replacing the use of dry ice with 6 refrigerant packs.

Important reminder: **place product in freezer** immediately upon opening this package, as directed

- Shipping capacity of 80 doses per container.
- Invoice and packing slip are separate from product, keeping them secure and dry.
- Diluent is conveniently located in the top layer of the box.
- Bubble bag provides added protection for the product.
- 6 refrigerant packs protect product on all sides to keep it stable and cold.
  - Replaces the use of dry ice during shipment.
  - Dispose of refrigerant packs with regular trash.
  - To maintain potency, the product must be stored frozen between –58°F and +5°F (–50°C to –15°C)
  - Do not store on dry ice. Use of dry ice may subject product to temperature colder than –58°F (–50°C).

If you have any questions, call 1-877-VAX-MERCK (1-877-829-6372) to speak with a Vaccine Account Representative.

MERCK

Introducing a new package for ZOSTAVAX (Zoster Vaccine Live)

Replacing the use of dry ice with 6 refrigerant packs

Important Reminder: **Place product in freezer** immediately upon opening this package as directed.

- Shipping capacity of 80 doses per container.
- Invoice and packing slip are separate from product, keeping them secure and dry.
- Diluent is conveniently located in the top layer of the box.
- Bubble bag provides added protection for the product.
- 6 refrigerant packs protect product on all sides to keep it stable and cold.
  - Replaces the use of dry ice during shipment.
  - Contains non-toxic, biodegradable gel. Dispose of refrigerant packs with regular trash.
  - To maintain potency, the product must be stored frozen between –58°F and +5°F (–50°C to –15°C).
  - Use of dry ice may subject product to temperature colder than –58°F (–50°C).

If you have any questions, call 1-877-VAX-MERCK (1-877-829-6372) to speak with a Vaccine Account Representative.

ZOSTAVAX®
Zoster Vaccine Live

MERCK

VACC-1005743-0002 06/11-ZOS

Colorado Department of Public Health and Environment, Immunization Section

Transporting Vaccines

Guidelines for transporting/short-term storage of vaccines

The procedure outlined below will keep all vaccines (including varicella-containing vaccines*) within recommended storage temperatures for 12 hours during transport and/or storage at room temperature. It will also maintain recommended temperatures if the cooler is exposed to outside temperatures as low as –4°F for one of those 12 hours..

* The Varicella-containing vaccine must be refrigerated (and NOT re-frozen) after transport, be sure that the refrigerators have maintained temperatures between 35 F and 46 F (2 C-8 C) for at least 3 to 5 days.

Assemble Packing Supplies

1. **Cooler:** Use hard plastic Igloo-type coolers. Attach a "Vaccines: Do Not Freeze" label to the cooler.
2. **"Conditioned" cold packs:** Condition frozen gel packs by leaving them at room temperature for 1 to 2 hours. (Until the edges have defrosted and the packs look like they have been sweating"). Cold packs that are not conditioned can freeze refrigerated vaccine. **Do not use dry ice.**
3. **Thermometer:** Prepare the thermometer by placing it in the refrigerator at least 2 hours before you pack the vaccine.
4. **Packing materials:** Use at least two 2-inch layers of bubble wrap, or similar packing material. Not enough packing material can cause refrigerated vaccine to freeze.

Pack the vaccine

1. Cold Packs

Spread conditioned cold packs to cover only half of the bottom of the cooler.

2. Bubble Wrap & Thermometer

Completely cover the cold packs with a two inch layer of bubble wrap.
Place the thermometer/ probe on top of the bubble wrap directly above a cold pack.

3. Vaccine

Stack layers of vaccine boxes on the bubble wrap. Do not let boxes touch the ice packs.

4. Bubble Wrap

Completely cover the vaccine with another 2-inch layer of bubble wrap.

5. Cold Packs

Spread "conditioned" cold packs to cover only half the bubble wrap. Make sure the cold packs do not touch the vaccine boxes.

6. Form & Display

Fill the cooler to the top with bubble wrap. Place the thermometer display and the Vaccine transfer form on top.

As soon as you reach your destination, or before returning the vaccine(s) to the storage unit(s) check the temperature!

If the vaccine temperature is:

* Between 35°F and 46°F, place the vaccines in the refrigerator, including all vaccines previously frozen. Label previously frozen vaccines containing varicella to be used within 72 hours.
* Below 32°F or above 46°F, label the vaccines "DO NOT USE", place them in the refrigerator, and contact the VFC program immediately, at 1-303-692-2650.

www. ColoradoVFC.com

The mission of the Immunization Section is to ensure the prevention of vaccine-preventable diseases in Colorado by increasing and maintaining vaccine coverage and assuring access to immunization services.

Leadership Changes for CIP

Transition to Public Health Director at CDPHE

I am writing to share news! I am so excited to have been selected for the new Public Health Director position at CDPHE effective July 1st. I am going to be working with a great team under the leadership of Dr. Chris Urbina. I really am looking forward to the new challenge and working across the many public health programs! In this new position, I will be responsible for the leadership of the Public Health side of our agency. I will be overseeing all of the Public Health programs, including Disease Control and Environmental Epidemiology, Prevention Services, Health and Environmental Information and Statistics, the State Lab, the Board of Health, Emergency Preparedness and Response and Health Facilities/ Emergency Medical Services. This will be a great opportunity and challenge for me!

I will be working on a transition plan over the next couple of weeks. I expect there will be an interim IMM Director named before July 1st. I will also be working with Dr. Lisa Miller to look for a new IMM Director as soon as possible. As you know there are many exceptional individuals within IMM and I have complete confidence they will continue their outstanding work. I have been privileged to work with so many talented and dedicated individuals during my 10 years with IMM. I am going to miss working with them day to day but know I will be still connected.

I realize there are many projects in "process" and I am committed to continuing to guide and support the projects to completion. I will not stop my work abruptly on the projects, as I will work with the interim appointee and eventually the new IMM director to see the projects to completion (or transition). While I will be involved, it will be different to be a couple steps removed from the day-to-day IMM work.

I look forward to working with you in my new role and in the continuing IMM projects. If you need anything, please connect with me at joni.reynolds@state.co.us or
(303) 692-2363. I will provide another update when the interim IMM Director has been named.

Best always!

Joni

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